

EC Certificate
Directive 98/79/EC Annex IV, excluding Sections 4 and 6
Full Quality Assurance System
In Vitro Diagnostic Medical Devices

Registration No.: HL 60091764 0001

Report No.: 21178021 006

Manufacturer: LifeCodexx AG
Jakob-Stadler-Platz 7
78467 Konstanz
Deutschland

Products: IVD software for prenatal diagnostics
- PrenaTest DAP.plus
The conformity assessment of the Notified Body is limited to aspects associated with the risk evaluation for trisomy 21.
(see attachment for site included)
Replaces Certificate, Registration No.: HL 60086622 0001

Expiry Date: 2017-06-21

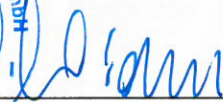
The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Effective Date: 2014-02-03

Date: 2014-02-03



Notified Body


Dipl.-Ing. C. Wiora

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HL 60091764 0001
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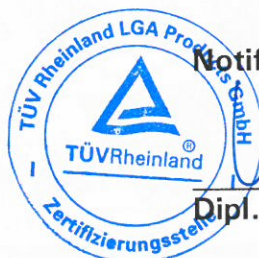
Manufacturer: LifeCodexx AG
Jakob-Stadler-Platz 7
78467 Konstanz
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site included:

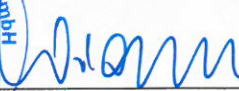
Lifecodexx AG
Line-Eid-Str. 3, 78467 Konstanz, Germany

Activities related to non-laboratory related activities for product realization, management commitment, to the management of resources, the quality management system, as well as measurement, analysis and improvement of the quality management system.

Date: 2014-02-03



Notified Body


Dipl.-Ing. C. Wiora